Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The therapeutic role of computer Interactive Binocular game in cases of mild to moderate refractive amblyopia

Protocol summary

Study aim
A comparative study and evaluation of the effect of computer game designed with two-eye vision stimulation separation for the treatment of patients with mild to moderate amblyopia and compare it with traditional patch therapy

Design
Two arms parallel group randomized Clinical trial design of 44 patients.

Settings and conduct
Children with a definite anisometropic amblyiopia are randomly divided into two groups A and B, and for one group ,patch therapy and for other group, anaglyphic glasses with game are used. The two groups will be evaluated 5 times in three months. Finally, two methods of treatment are compared with the standard software.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Children aged 4 to 12 years with mild-to-moderate anisometropic amblyopia who had not previously been treated with amblyopia and whose parents were willing to enter the study. Exclusion criteria: Patients with amblyopia with other causes (non-refractive), neurological motor disorder and brain lesions that do not have the ability to work with computers and do not play.

Intervention groups
In the case group, treatment of amblyopia is performed with anaglyphic glasses with red and green glasses placed in front of the lazy eye and healthy eyes, along with a game designed for a 3-month period. In the control group, the amblyiopia is treated with patch therapy according to conventional procedures and lasts for 3 months (according to the abmlyiopia treatment study protocol).

Main outcome variables
In two groups, the examinations consist of best corrected visual acuity, depth of vision (streopsis) and fusion, testing at pre-treatment intervals, two weeks after the start of treatment, one, two, and three months after the start of treatment, five times in total.

General information

Reason for update
lack of access to anaglyph glasses and delay in starting the study

Acronym

IRCT registration information
IRCT registration number: **IRCT20180217038768N1**
Registration date: **2019-04-22, 1398/02/02**
Registration timing: **prospective**

Last update: **2021-08-27, 1400/06/05**
Update count: **2**

Registration date
2019-04-22, 1398/02/02

Registrant information

Name
Jaber Mohseni

Name of organization / entity

Country
Iran (Islamic Republic of)

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Mohsenij951@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-05-31, 1398/03/10

Expected recruitment end date
2021-09-30, 1400/07/08

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The therapeutic role of computer Interactive Binocular game in cases of mild to moderate refractive amblyopia

Public title

Effect of computer game in treatment of amblyopia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children aged 4 to 12 years old Children with anisometropic amblyopia (amblyopia in the presence of a spherical equivalent ≥0.50 diopter between the two eyes or the difference in stigmatism in any meridian ≥1.50 diopter) with mild to moderate severity Children who have not previously been treated with ambiopia. Children whose parents have the consent to enter the study.

Exclusion criteria:

Patients with amblyopia with other causes (non-refractive) Patients with motor neurological disorder and brain lesions that do not have the ability to work with the computer and do not play.

Age

From **4 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Unfortunately, due to the nature of the intervention, the use of special glasses does not allow patients to blind. But the optometrist will be unaware of the patient grouping. Patients will be rendered using envelopes, and patients will fall into one of two groups, A or B, according to the accident. An individual who groups patients does not know the nature of Group A or B.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Before starting a study in a 3-month period, an amblyopia treatment pilot game will be performed in eligible patients.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Khatam Al Anbia Hospital, Gharani street

City

Mashhad

Province

Razavi Khorasan

Postal code

91778-99191

Approval date

2018-02-28, 1396/12/09

Ethics committee reference number

IR.MUMS.fm.REC.1396.783

Health conditions studied

1

Description of health condition studied

anisometropic amblyopia

ICD-10 code

H52.31

ICD-10 code description

Anisometropia

Primary outcomes

1

Description

Best corrected visual acuity

Timepoint

Measuring the Best corrected visual acuity at the beginning of the study (before the intervention), two weeks, one month, two months and three months after the intervention began.

Method of measurement

Measuring the Best corrected visual acuity by early treatment diabetic retinopathy study chart, according to the crowded protocol

Secondary outcomes

1

Description

Stereopsis

Timepoint

Measuring the stereopsis at the beginning of the study (before the intervention), two weeks, one month, two months and three months after the intervention began.

Method of measurement

Measuring the stereopsis by Randot stereo test

2

Description
fusion
Timepoint
Measuring the fusion at the beginning of the study (before the intervention), two weeks, one month, two months and three months after the intervention began.
Method of measurement
Measuring the fusion by Worth four dot test

3

Description
Phoria and tropia
Timepoint
Measuring phoria and tropia at the beginning of the study (before the intervention), two weeks, one month, two months and three months after the intervention began.
Method of measurement
Measuring of phoria and tropia by cover uncover test, alternate prism and cover test, hirschburg, krimsky

Intervention groups

1

Description
Intervention group: Based on the principle that the lazy eye should be exposed to more complex and moving images and static images for the stronger eyes, a computer game designed to enhance binocularity in another design is designed by the main executor. The images in this game are designed to be used with special glasses to filter out green and red images for strong and lazy eye respectively. Also, in order to stimulate the lazy eye, at each step, the speed of moving images increases and their contrast will change.The game will be installed on a tablet or mobile device, and with the red green glasses for this game, it can be seen with the separation of moving red and static green images (anaglyphics). In the intervention group, patients (with the help of their parents) are asked to take 30 minutes twice daily (once an hour) for 5 days a week for 4 weeks and then two days a week for 8 weeks (total 36 hours) for the child Use a computer game within three months. Children should wear anaglyphic glasses with their glasses when playing.
Category
Treatment - Devices

2

Description
Control group:In the control group, patch therapy is performed according to conventional procedures and continues for 3 months (according to the Ambliopia Treatment Study).
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Khatam Al Anbia Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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School of Pharmacy, Nanotechnology Research Center, Mashhad University of Medical Sciences
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Grant name
Mashhad university research unit
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Jaber Mohseni

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

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Subspecialist

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Jaber Mohseni

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

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mohsenij951@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available